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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|------------------|------------------------|-----------------------|------------------|
| 10/792,178 | 03/03/2004 | David E. Francischelli | P-8575.06 | 4900 |
| 27581 MEDTRONIC | 7590 01/09/2008 | | EXAMINER | |
| MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE | | | VRETTAKOS, PETER J | |
| MINNEAPOLI | S, MN 55432-9924 | | ART UNIT PAPER NUMBER | |
| | | | 3739 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 01/09/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|---|---|----------------------|--|--|--|--|
| | 10/792,178 | FRANCISCHELLI ET AL. | | | | |
| * Office Action Summary | Examiner | Art Unit | | | | |
| | Peter J. Vrettakos | 3739 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on <u>27 November 2007</u> . | | | | | | |
| 2a) This action is FINAL . 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>25-33 and 62-79</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) <u>62-79</u> is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>25-33</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application 6) Other: | | | | | | |

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DETAILED ACTION

The action is non-final.

RCE filed 11-27-07.

Claims 25-33 are rejected.

Claims 62-79 are withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-26 and 28-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Nardella (5,733,281).

Re: claims 25-26, 28, 31: Nardella discloses a method of tissue ablation comprising positioning an electrode (energy delivering electrode, patented claim 1, 12), supplying electrical power (electrosurgical energy, 40), sensing with a sensor (20) the vibration of the tissue (piezoelectric ceramic crystal, patented claim 7; acoustic output signal, patented claim 3) and reducing/halting ("regulating", patented claim 3; power regulation element; col. 8:57-60) power when the vibration reaches a given value.

See col. 2:46-59 for disclosure toward an acoustical detection element, which anticipates detecting vibrations in tissue that is being treated during the ablation procedure. See col. 3:18-23 for disclosure toward regulating the power supplied to the

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device electrode in response to the acoustic output signal, which anticipates reducing power when the "vibration" detected in tissue during ablation treatment reaches a given value.

Re: claims 29, 30: Nardella discloses an output device (130) and an indicator signal (along 128). See figure 2 and col. 8:53-57 for disclosure toward the output device providing output when the sensed vibration is outside a specific/selected range.

Re: claim 32: PVDF in col. 7:36 is a piezoelectric polymer.

Re: claim 33: sensor (20) is integrated with the electrode (12) as depicted in figures 1-3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nardella (5,733,281) in view of Nardella (5,334,193).

Nardella ('281) incorporates by reference in col. 9:56 Nardella (5,334,193), which discloses *impedance* feedback control of fluid delivery to treated tissue (see '193 Abstract).

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Nardella ('281) discloses in one embodiment impedance feedback control of power delivery, and in another embodiment acoustic/vibration feedback control of power delivery. As such, Nardella establishes that impedance feedback control is a seamless substitution for acoustic/vibration control and vice versa.

Claim 27 discloses *vibration* feedback control of fluid delivery to treated tissue. The Office argues that Nardella ('281) (impedance/vibration feedback control of power) in light of Nardella ('193) (impedance feedback control of fluid delivery) makes obvious vibration feedback control of fluid delivery to treated tissue thereby making obvious at the time of the Applicant's invention, claim 27, the motivation to add vibration feedback control of fluid to Nardella ('281) to optimize the ablation procedure for reasons seen in Nardella ('193).

Response to Arguments

Applicant's arguments filed 11-27-07 have been fully considered but they are not persuasive. Nardella discloses an ablation method using vibration feedback. The source of the vibration includes that that is self-generated (and not merely that emitted by Nardella's transducer). Nardella detects the effects of energy on tissue (self-generated) such as the generation of steam created during energy application/heat generation. See col. 2: 48-55. Nardella's transducers emit a pulse and the tissue reflects that pulse, which is sensed. Self-generated vibrations due to ablation affect the emitted pulse during the reflection and therefore the vibration feedback system is controlled by self generated vibrations as well as transducer emitted pulses. To say otherwise is to argue

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that the Applicant's ablation causes self-generated waves in the tissue, but Nardella's does not. This defies logic. How does the Applicant's ablation differ from Nardella's?

The waves generated by ablation in Nardella inherently affect the emitted wave from the transducer. As such the rejection stands.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Pete Vrettakos

December 24, 2007

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PRIMARY EXAMINER